maintaining the patency of a lumen rather than occluding it (see, e.g., col. 1, ll. 7-12). Hess therefore does not disclose any elements relating to tissue growth. In fact, Hess teaches away from tissue growth because its stated novel feature is its ability to be collapsed and removed from a vessel—which would be impossible or ineffective if there was any tissue growth into or around the stent.

Applicants also responded to the Examiners' concerns noted in the Office Action and in the interviews regarding Applicants' support for the interference claims in the 6,176,240 parent patent (Applicants are claiming priority back to 1995 for the interference claims to ensure their senior party status in each of the potential interferences).

Based on discussions with Examiners Odland, Ragonese and Bennett, it appeared that the Examiners' support concerns revolved around whether the '240 parent patent contained support for the claim terms relating to expansion from a first tubular configuration to a second larger tubular configuration. In the interview, Applicants noted that—while they believe such support exists in the '240 patent—they need not rely on that patent for priority to 1995 because they also have support in parent application Ser. No. 08/475,252 which was filed on June 7, 1995 (the same day as the application which led to the '240 patent).

In the interview, Applicants explained the '252 application's support for the expansion claim terms with reference to the embodiment depicted in Figure 6.[1] The application describes how the device is initially in a configuration "which is less than the inner diameter of the fallopian tube" for insertion (p. 8, ll. 27-32), is restrained in this configuration, for example, by a catheter (p. 12, ll. 13-15) and then, when released, "protrudes sufficiently to firmly engage the tubal wall" (p. 5, ll. 25-27).

In addition to the '252 application's clear support for the expansion terms at issue (and the fact that the '252 disclosure is incorporated by reference into the '240 patent) Applicants believe that the '240 patent itself supports the expansion claim terms. For example, the device is depicted in its initial tubular configuration in Figure 4 and is described as having "an outer diameter . . . which is less than the inner diameter of the fallopian tube" (col. 5, ll. 33-34). When the device is deployed, it again assumes a tubular configuration (see, e.g., Fig. 6—which shows

[1] If the '252 file wrapper is not readily available, see WO 96/40024 (the only publication of the '252 application because the application was abandoned—but not before a continuation-in-part was filed).

the majority of the device following the general shape of the fallopian *tube*). And, this second tubular configuration must be larger in order to engage the fallopian tube (see, e.g., col. 5, ll. 28-29: "clearly, the secondary shape must have a larger outer diameter than the inner diameter of the fallopian tube").

The '240 patent's support for the expansion terms at issue is further evidenced by the disclosure at column 3, lines 26 to 37. The specification here discloses a primary coil (which is most easily formed as a "straight cylindrical coil", i.e., a first tubular configuration) which is given a secondary shape through bending. This bending affects the second configuration that the device will assume upon deployment in the fallopian tube. The bends that are imposed on the primary coil are disclosed at lines 32 to 34 as potentially taking a wide variety of forms including "sinusoidal curves, *the individual loops of a continuous secondary coil*, or the like" (emphasis added). This disclosure makes it clear that the secondary shape may also be a continuous coil—with bends imposed on the individual loops of that coil. Moreover, these bends must result in the overall diameter of the coil increasing (in order to engage the walls of the fallopian tube as discussed above).

In addition to these expansion limitations, the claims at issue generally recite two additional elements—one relating to the tubular shape of the device and another relating to tissue growth. The limitations related to tubular shape are plainly disclosed in each of the '779 and '252 applications. For example, see Figures 1 and 4 of U.S. Patent No. 6,176,240 (the patent which issued from the '779 application) and Figures 1, 2, 3, 6 and 7 of WO 96/40024 (the only publication of the '252 application because the '252 application was abandoned—but not before a continuation-in-part was filed).

And, finally, both of Applicants' 1995 applications have support for the limitations relating to tissue growth. For example, both of the applications provide that "the present invention further encompasses devices which promote tissue growth within the tube to induce tubal occlusion, further inhibiting conception" (see, e.g., col. 5, ll. 15-17 of the '240 patent and p. 8, ll. 21-24 of the '252 application). In addition, the '240 patent discloses that "polyester fibers such as Dacron™, Rayon™, or the like, are bonded to the surface of primary coil 12 using a polymeric adhesive. The polyester fibers promote increased tissue growth around the coil" (col. 6, ll. 13-17 of the '240 patent—which is incorporated by reference into the '252 application).

Applicants therefore believe they have demonstrated support in both of their 1995 applications for each of the terms in each of the pending claims.

Claim Rejections

Claims 12-81 are pending in the instant application. In the Office Action mailed December 20, 2004, the Examiner rejected each of these claims. Based on the remarks made herein and the discussions between the Examiners and Applicants' representatives at the interview on June 6, 2005, Applicants respectfully request that the rejections be withdrawn and the claims be allowed. Applicants also respectfully request action on the pending request to provoke an interference between the instant application and application 08/770,123 if interfering claims are allowed in each application. Applicants also wish to remind the Examiner that pending claims 12-21 are copied from or correspond to claims in U.S. Patent No. 6,096,052.

Claim Rejections Under § 102

Paragraphs 2 and 3 of the Action reject claims 12-14, 19-53, 66-71, 73-79 and 81 under 35 U.S.C. § 102(b) as being anticipated by Pinchuk in U.S. Patent No. 5,163,958. Applicants respectfully traverse the rejection because Pinchuk fails to teach, suggest or disclose all elements of the claims for at least the reasons described below.

The preamble of each of the rejected claims recites a contraceptive and/or sterilization device or system. In addition, each of the claims recites *in its body* at least one (and usually two or three) limitations that expand on the contraceptive and/or sterilization device stated in the preamble. Such limitations include tubular members that are secured to the fallopian tube or to a reproductive system lumen and/or are expandable within the fallopian tube or a reproductive system lumen. Other claims specifically recite a contraceptive device in the body of the claim or contain limitations such as occlusion to disrupt conception or to prevent passage of reproductive cells. These contraceptive limitations, contained in the preamble and the body of each of the rejected claims, represent at least one difference between these claims and the Pinchuk patent. Pinchuk discloses a device which is intended for use in blood vessels—and makes no mention of the reproductive system or contraception. While the Action notes that intended use does not hold patentable weight in apparatus claims, the elements mentioned above relating to the reproductive system are limitations that can not be read out of the claims. In addition, the "contraceptive

device" and "sterilization device" preamble phrases are given life and meaning by the aforementioned elements recited in the body of each claim and are therefore limitations which must be disclosed in the reference in order for it to be anticipatory. Pinchuk fails to teach, suggest or disclose the elements recited in each of the rejected claims which are described above as relating to contraception, sterilization or the reproductive system.

Furthermore, claims 12-14, 19-21, 35-37, 73 and 76 recite members or elements which cause occlusion of a reproductive lumen or the fallopian tube. Contrarily, the purpose of the Pinchuk device is to prevent occlusion and to maintain patency of the lumen (see, e.g., col. 1, ll. 32-36 and col. 6, ll. 4-7). Pinchuk therefore does not teach, suggest or disclose the members / elements which cause occlusion in claims 12-14, 19-21, 35-37, 73 and 76. The Action refers to Pinchuk's disclosure of endoprostheses being used to treat aneurysms as disclosing occlusion (col. 1, ll. 25-30), however, Pinchuk specifically discloses these devices as treating "stenoses, stricture, aneurysm conditions and the like." Because the use of endoprostheses / stents for the treatment of aneurysms is "like" the use of stents for the treatment of stenoses and stricture (i.e., the object of each is to maintain blood flow through a lumen), disclosure of the aneurysm treatment use does not meet the occlusion limitations.[2] Pinchuk therefore fails to teach, suggest or disclose the recited elements in each of claims 12-14, 19-21, 35-37, 73 and 76.

Claim Rejections Under § 103

Paragraph 3 of the Action rejects claims 22-25, 27-34, 40-47, 49, 51-53, 66-71, 73-79 and 81 under 35 U.S.C. § 103(a) as being obvious in view of Pinchuk. Because Pinchuk fails to disclose each of the elements of the rejected claims as detailed above and does not provide a motivation to modify its stent design to create a contraceptive device (which would have the opposite purpose of closing, rather than opening, a lumen) it can not render the claims obvious.

Paragraph 5 of the Action rejects claims 15-18, 54-65, 72 and 80 under 35 U.S.C. § 103(a) as being rendered obvious by Lan (CN 1073088) in view of Pinchuk (U.S. Patent No. 5,163,958). The device disclosed in Lan is essentially a contraceptive plug with various notch

[2] An aneurysm is a dilation/expansion in the wall of a blood vessel. Because the walls in the dilated portion of the blood vessel have thinned, they are weak and may burst if blood is allowed to flow into and put pressure on them. Pinchuk-like stents are thus used to provide a flow path for the blood which bypasses the aneurysm, protects the thin blood vessel walls and promotes thrombosis.

designs along its perimeter which enhance its ability to remain lodged in a fallopian tube. Because Lan does not overcome the above-noted deficiencies of Pinchuk, the combination of Lan and Pinchuk fails to teach every element of the rejected claims. Furthermore, the Action cites no motivation to combine the teachings of Pinchuk with Lan.

Double Patenting Rejections

Claims 12-81 have been rejected under the judicially created doctrine of obviousness type double patenting over U.S. Patent No. 6,684,884 and provisionally rejected over U.S. App. Nos. 10/641,333 and 10/779,541. As per the Examiner's suggestion, and without admitting that these double patenting rejections are proper, Terminal Disclaimers in compliance with 37 CFR 1.321(c) are enclosed, obviating this rejection.

Information Disclosure Statement

In the Office Action mailed December 20, 2004, the Examiner indicated that the non-patent literature documents were missing from the IDS filed August 29, 2003. Submitted with this response is a new Information Disclosure Statement in which copies of the previously omitted documents are provided. Applicants request that the Examiner consider these references as part of the examination of this application.

Request for Extension of Time

Applicants respectfully request an extension of time to respond to the pending Office Action, and a check for the necessary extension fee is enclosed.

CONCLUSION

In view of the above remarks, reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 102 and 103 are respectfully requested. Moreover, it is respectfully submitted that all of the presently presented claims are in form for allowance and such action is earnestly solicited.

If any additional fees are required for this response, please charge Deposit Account Number 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN

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